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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1638	

DATE MAILED: 08/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/978,274	THOMAS ET AL.	
	Examiner	Art Unit	
	Medina A. Ibrahim	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *46-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *46-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's response filed 05/19/05 in reply to the Office action of 11/16/04 has been entered. Claims 1-4, 22-24, 28-29, 31, 33-34, 36-45 are cancelled, and new claims 46-65 are added. Therefore, claims 46-65 are pending and are examined.

The references of Hey et al (Plant Physiol. (1995) 107:1323-1332) and Stripe et al (Biotechnology, Vol. 10, pp. 405-412 (1995)) have been considered.

All previous rejections and objections not set forth below have been withdrawn in view of Applicant's amendment. The art rejections have been withdrawn in view of Applicant's arguments as set forth in page 12 of the response.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Objections

At claims 47-49, and 53, it is suggested that "binds" be replaced with ---hybridizes---, for clarification that nucleic acid sequences hybridize to each other.

At claim 62, it is suggested that "the inducible promoter is inducible by nematode feeding" be replaced with ---the promoter is nematode inducible---, for clarification.

At claim 56, "molecule" should be changed to ----DNA molecule---, for clarification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 46-65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 46-50, 56, 59-60, 63-65 are indefinite because it is unclear what is encompassed by "allowing natural development of a plant" or how to allow "natural development" of a plant. Clarification is required to more clearly define the metes and bounds of the claims. Dependent claims 51-55, 57-58, and 61-62 are included in the rejection.

Claim 56 is indefinite because "said specific cells" and "said plant" in part (ii) lack antecedent basis.

Claims 47-49, and 53 are indefinite for failing to recite specific hybridization and wash conditions. Hybridization conditions vary from one laboratory to another, and what is stringent for one may not be stringent for another. The instant specification fails to clearly set forth Applicant's "stringent" conditions. At the paragraph bridging pages 11 and 12 of the specification, Applicant only provides exemplary stringent conditions. Since there are several different ways to define "stringent conditions, one would not know what is encompassed by the claims. Dependent claims 54-55, 61-62 are included in the rejection.

At claims 47-50, 53, and 60, "capable of inducing cell death" renders the claims

indefinite because "capable" implies the PAP molecule may or may not induce cell death. The instant specification fails to describe the conditions under which cell death may not be induced. If Applicant intends the PAP molecule induces cell death, it is suggested that "capable of inducing" be replaced with ----induces-----.

At claim 51, "a Pro-PAP-S" implies that there is more than one Pro- PAP-S, and it is unclear if there is more than one.

At claim 58, "a mature PAP-S protein", "a Pro-PAP-S", " a PAP-S α " and " a PAP-Sβ" imply that there are more than one Pro- PAP-S, more than one mature PAP-S protein, more than one Pro-PAP-S, more than one PAP-S α, and more than one PAP-Sβ. However, it is unclear if there is more than one of each of said PAP proteins. Clarification is required to more clearly define the metes and bounds of the claim.

Claim 60 is indefinite for lacking correlation between the preamble and the last method step. The claim is drawn to method of inducing necrotic effect in specific cells of a plant, and the last step is inducing cell death. Appropriate correction is required to more clearly define the metes and bounds of the claims.

At claim 61, "the inducible pathogen" lacks antecedent basis. It is suggested "inducible" be deleted.

Claim Rejections - 35 USC § 112

Claims 46-65 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of inducing nematode resistance in a transgenic plant by introducing a chimeric gene comprising the pokeweed antiviral

protein (PAP) encoding sequences of SEQ ID NO: 1, 3, 5, or 7 under the control of a nematode inducible promoter in a transgenic plant, and plants and plant cells produced by said method, does not reasonably provide enablement for a method of inducing cell death in any plant cells with exemplified or non-exemplified pokeweed encoding nucleic acids. This rejection is repeated in part for the reasons of record as set forth in the last Office actions of 11/16/04. Applicant's arguments filed 05/19/05 have been considered but are not deemed persuasive.

The claims are drawn to a method of inducing cell death in specific cells of a plant, said method comprising exposing a plant comprising a chimeric gene comprising a nucleic acid encoding pokeweed antiviral protein including Pro-PAP-S, PAP-S, PAP-S α and PAP-Sβ encoding nucleic acids, and a pathogen or chemical or plant developmental inducible promoter, wherein the expression of said pokeweed antiviral protein induces cell death in said specific cells. The claims are also drawn to said nucleic acid hybridizes under stringent conditions to SEQ ID NO: 1, 3, 5 or 7 and encodes PAP capable of inducing cell death. The claims are further drawn to said method wherein the promoter is induced in pollen cells, anther cells, tapetum cells, ovule cells, nematode feeding cells, abscission zone cells, sepal cells, carpel cells, stamen cells, trichome cells or seed cells. The claims are also drawn to a plant produced by said method.

Applicant teaches cloning and sequencing of nucleic acids from pokeweed leaf encoding pokeweed antiviral protein (SEQ ID NO: 2, 4, 6, and 8). Applicant also teaches constructs containing PAP-S sequences under the control of 35S CaMV for

transient assay in tobacco protoplasts to show PAP-S mediated ribosome inactivation. (Figures 5-7). Applicant also teaches transformation of tobacco and potato with nucleic acid encoding the pokeweed antiviral protein of SEQ ID NO: 2 or 4 under the control of a nematode inducible promoter and expression of Pro-PAP-S or mature PAP-S in nematode infected root cells. Applicant teaches transformation of tobacco with Pro PAP-S encoding sequence and potato plants with mature PAP-S or Pro-PAP-S sequences resulted in transgenic tobacco and potato plants with nematode resistance (Figures 11 and 12). However, Applicant states that several attempts to transform tobacco cells with mature PAP-S sequence failed to produce transformed tobacco cells showing that the mature PAP-S sequence does not function in tobacco plants. Applicant also teaches assays for testing whether a nucleic acid encoding PAP possesses ribosome-inactivating activity in a plant.

Applicant, however, does not provide guidance for a method of inducing cell death in specific cells of a plant using exemplified or non-exemplified pokeweed encoding nucleic acids with exemplified or non-exemplified inducible promoters. No transgenic plant or plant cells with induced cell death as result of expressing exemplified or non-exemplified nucleic acids have been disclosed. Neither the instant specification nor the prior art provides evidence showing that all plant ribosome-inactivating proteins or RIP 1 proteins inherently induce cell death in plant cells expressing said proteins. In addition, the instant specification does not provide guidance for promoters other than nematode inducible promoters that functions with any PAP encoding nucleic acids in

transgenic plants. The specification does not teach how to properly target a functional pokeweed antiviral protein into specific plant cells to induce cell death.

Nielson et al (Annu. Rev. Plant Physiol. Plant Mol. Biol. (2001), vol. 52, pp. 785-816) teach about ribosome inactivating proteins including pokeweed, their enzymatic activities, and their complex biological role. Nielson et al specifically states that while plant RIPs have been linked to antiviral, antifungal and insecticidal activity in transgenic plants, the mechanism of these effects remains unresolved (see at least the Abstract on page 785). The paragraph bridging pages 801 and 802, the cited reference states "(a)lthough the enzymatic mechanism of RIP activity is well defined, the physiological steps by which ribosome inactivation leads to cell death are not well understood".

The prior art teaches that transformation of a plant with a PAP encoding nucleic acids is highly unpredictable. For example, Lodge et al (PNAS, vol. 90, pp.7089-7093, 1993, Applicant's IDS) teach that the expression of PAP in transgenic plants may result undesired phenotype such as stunted, molted and sterility in the plant. Lodge et al teaches that tobacco plants expressing high levels (above 10ng/mg of protein) of wild type and mutant PAP tend to have stunted and mottled phenotype, and some the plants were sterile (see page 7090, Results and Discussion). On the other hand, Barbieri et al (Biochemica et Biophysica Acta, vol. 1154, pp. 237-282, 1993, Applicant's IDS) teaches that plant RIPs including PAP can act on their ribosome only at high levels of concentrations (see pages 251-252, section III-A). Another example is Tumer et al (PNAS, vol. 94, pp. 3866-3871, 1997, Applicant's IDS) who teach transgenic tobacco plants expressing high levels of PAP with point mutations showed growth reduction and

lesions on their leaves (Fig. 3 on page 3868), while transgenic plants expressing high levels of active site mutant PAP didn't show antiviral activity, and while transgenic plants expressing low levels of C-terminal deletion mutant were resistant to virus and showed normal growth (Table 2, page 3870).

In addition, the working examples disclosed in the specification are limited to the use of nucleic acids encoding pro-PAP-S (SEQ ID NO: 2), mature PAP-S (SEQ ID NO: 4), PAP-S α (SEQ ID NO: 6), and PAP-Sβ (SEQ ID NO: 8). The ability of pro-PAP-S or mature PAP-S (including PAP-S α and PAP-Sβ) to induce ribosome nematode resistance in transgenic plants/cells cannot be extrapolated to all PAP encoding sequences including those that hybridize to SEQ ID NO: 1, 3, 5, or 7 under any stringent conditions. It is unpredictable as to whether a nucleic acid that hybridizes to SEQ ID NO: 1, 3, 5, or 7 under "any stringent" conditions will encode a functional polypeptide having the functional activity of SEQ ID NO: 2, 4, 6, or 8.

Therefore, given the breadth of the claims, the state of the prior art regarding role of plant RIPs in inducing cell death; the nature of the invention; the limited working examples, and the unpredictability with respect to PAP activity in transgenic plants as discussed above, the claimed invention is not enabled throughout the broad scope. See In re Wands 858 F.2d 731, 8USPQ2nd 1400 (Fed. Cir, 1988).

Response to Arguments

Applicant correctly states that the test for enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. Applicant

asserts that all pending claims in this application satisfy the enablement requirement of 35 USC 112, 1st paragraph.

This assertion is incorrect because the scope of claims is not supported by an enabling disclosure, taking into account the *In re Wands* factors as set forth in the last Office action of 11/16/04. Applicant has provided no clear and convincing evidence to support the conclusion that all pending claims satisfy the enablement requirement of 35 USC 112, 1st paragraph. Applicant has not provided a single method of inducing cell death in a transgenic plant using exemplified or non-exemplified DNA.

Applicant specifically argues that the instant specification discloses working examples using SEQ ID NO: 3, 5, and 7 and stringent hybridization conditions that may be used to isolate nucleic acids encoding pokeweed antiviral proteins that can induce plant cell death. Applicant also argues that assays for detecting nucleic acids encoding PAP having ribosome inactivating activity are taught in the specification. Applicant, therefore, asserts that one skilled can practice the claimed invention without undue experimentation (response, p. 9).

These arguments are not persuasive because the instant specification does not disclose a single nucleic acid with plant cell death inducing activity which can be used for the claimed method, and hybridization conditions would not provide information regarding nucleic acid with cell death inducing activity. While the specification teaches assays for detecting if a nucleic acid encodes a PAP with ribosome-inactivating activity, the claimed method requires that the PAP proteins induce cell death rather than ribosome inactivating activity. No transgenic plant cells with induced cell as a result of

expressing exemplified or non-exemplified PAP sequences have been disclosed. Neither the instant specification nor the prior art teaches a method or assays for detecting if a nucleic acid encodes a PAP having cell death inducing activity. Applicant provides no evidence that shows all plant ribosome-inactivating proteins inherently induce plant cell death.

The specification merely states that nucleic acids that are capable of hybridizing to SEQ ID NO: 1, 3, 5, or 7 can be obtained. However, it is not predictable as to whether these hybridizing nucleic acids will encode a functional PAP having plant cell death inducing activity since no nucleic acid encoding a PAP having cell death inducing activity has been disclosed. In addition, Applicant's response provides no evidence that shows the hybridizing property of a nucleic acid can be used to predict the function of the protein encoded by said nucleic acid. In addition, since the claims recite any "stringent conditions", one skilled in the art would not expect that the majority of nucleic acids obtainable under "any" low and moderate stringent conditions would encode a protein functionally related to SEQ ID NO: 4, 6 or 8. Applicant points to no specific hybridization conditions that would allow the specific isolation of nucleic acids other than SEQ ID NO: 1, 3, 5, or 7 encoding PAP having a cell death inducing activity. One would have to test all these nucleic acids in the myriad of transgenic plants transformed with each of these nucleic acids to determine which will induce specific cell death in a transgenic plant. These tests are considered undue, since one cannot predict the phenotypic effect of a nucleic acid when expressed in a transgenic plant.

In *Genentech Inc. v. Novo Nordisk* A/S (42 USPQ2d 1001 at p. 1005) The CAFC stated "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not workable...While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention...[W]hen there is no disclosure of any specific starting material or of any of the conditions under which a process can be carried out, undue experimentation is required.... It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement". Id. In this case, as in *Genentech*, the specification does not provide the "reasonable detail .....to enable members of the public to understand and carry out the invention" as broadly claimed.

Given that the broad scope of the claims encompassing a method that employs any and all nucleic acids encoding pokeweed antiviral protein and nucleic acids that hybridize to SEQ ID NO: 1, 3, 5, or 7 under any stringent conditions, and encoding PAP having cell death inducing activity in a transgenic plant; the limited working examples; the unpredictability inherent in expressing PAP in a transgenic plant as evidenced by Stripe et al. (Biotechnology, vol 10, pp. 405-412 (1992); Hey et al (Plant Physiology, vol. 107:1323-1332 (1995); Lodge et al; Barbieri et al; and Applicant's own specification teaches that a method for expressing a mature PAP-S under the control of a inducible promoter failed to produce transgenic tobacco plant, as disclosed in the last Office actions of 02/25/04 and 11/16/04; and the complex biological function of RIPs as

discussed above, the claimed invention is not enabled throughout the broad scope. Therefore, the rejection is maintained.

Written Description

Claims 46-65 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated in part for the reasons of record as set forth in the last Office actions of 11/16/04 and 0. Applicant's arguments filed 05/19/05 have been considered but are not deemed persuasive.

Applicant correctly states the factors to be considered when determining whether a claimed invention is sufficiently described. Applicant asserts that the instant specification provides both structural and functional features that sufficiently describe the pokeweed proteins of the claimed invention.

This is not persuasive because the claimed invention requires a multitude of nucleic acids encoding a multitude of proteins having plant cell death inducing activity and various pathogens, chemical and plant development inducible promoters. No structural property that relates a PAP encoding nucleic acid to cell death-inducing activity is known. Nielson et al (Annu. Rev. Plant Physiol. Plant Mol. Biol. (2001), vol. 52, pp. 785-816) teach that the biological role of plant RIPs is complex and that while plant RIPs have been linked to antiviral, antifungal and insecticidal activity in transgenic

plants, the mechanism of these effects remains unresolved (see at least the Abstract on page 785).

The *University of Rochester v. G.D. Searle* & Co., Inc.(, U.S. District Court, Western District of New York, Decision and Order No. 00-CV-6161L,) decided 05 March 2003, at page 8, bottom paragraph, that method claims are properly subjected to a written description requirement if the starting material which requires that method is itself inadequately described. The court specifically stated, "(T)he claimed method depends upon finding a compound that selectively inhibits PGHS-2 activity. Without such a compound, it is impossible to practice the claimed method of treatment. It means little to "invent" a method if one does not have possession of a substance that is essential to practicing that method. Without that substance, the claimed invention is more theoretical than real;..... and there is no meaningful possession of the method."

Applicant argues that the instant specification discloses stringent hybridization conditions that may be used to isolate additional nucleic acid sequences encoding PAP having ribosome inactivating activity, and that the working examples disclosed in the specification provide assays for testing whether a nucleic acid encodes a protein with RIP activity.

These are not persuasive because the stringent hybridization conditions for the isolation of nucleic acids encoding PAP having ribosome inactivating activity and assays for detecting ribosome-inactivating activity would not provide information regarding the written description of the nucleic acid required for the claimed invention. In addition,

"any stringent conditions" as recited in the claims are not expected to yield nucleic acids that are structurally and functionally related to SEQ ID NO: 1, 3, 5, or 7. In addition, the disclosed sequences encode PAP having ribosome inactivating activity rather than cell death inducing activity.

Applicant has not described a structural property the relates the disclosed sequences to cell death inducing activity. Therefore, it is apparent that applicant was not in possession of the invention as claimed.

Applicant further argues that it was known in the art that all type I ribosome-inactivating proteins from unrelated plant species existed with structural similarities. Applicant cites Stripe et al (1992) to support this position.

This is not found persuasive because the rejected claims are not drawn to ribosome inactivating proteins from plants and their structural similarities, but rather to a method of inducing cell death in specific plant cells by transforming the plant with nucleic acid encoding any PAP. The paragraph bridging columns 1 and 2 of page 407, however, Stripe et al (1992) teach that the total sequence similarity among RIPs is 15% to 30%. Therefore, Stripe et al do not support Applicant's position.

Given the lack of written description of the nucleic acids and promoters required for the claimed invention, the state of the prior art as evidenced by Stripe et al (1992), and unpredictability inherent in expressing PAP in transgenic plants as discussed above, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that one skilled in the art would recognize that Applicants are in possession of the invention. Therefore, the rejection is maintained.

Hey et al (Plant Physiol. (1995) 107:1323-1332) teach maize ribosome-inactivating protein and pokeweed antiviral protein as its homolog and roles of these proteins in plant viral and fungal resistance. Hey et al do not teach or suggest transformation of plants with pokeweed to induce cell death in specific plant cells. Therefore, Hey does not appear to support Applicant's position regarding the above rejection.

Stripe et al (Biotechnology, Vol. 10, pp. 405-412 (1995)) teach ribosome inactivating proteins from plants. Stripe et al do not teach or suggest do not teach or suggest transformation of plants with pokeweed to induce cell death in specific plant cells. Therefore, Stripe does not appear to support Applicant's position regarding the above rejection.

Claim Rejections - 35 USC § 102

Claim 56 is rejected under 35 U.S.C. 102(b) as being anticipated by Kaniewski et al (US 6, 015,940).

The claim is directed to a molecule comprising a nucleic acid molecule encoding a mature pokeweed antiviral protein and inducible promoter which induces expression of said mature pokeweed in specific cells upon exposing said plant to a pathogen or a chemical or through natural development of said plant.

Kaniewski et al teach a DNA molecule comprising a DNA encoding a mature PAP and inducible or tissue specific promoter for expression of pokeweed in specific plant cells (see column 8-9). Therefore, Kaniewski et al teach all claim limitations

Remarks

Claims 46-55 and 57-65 are deemed free of the prior art of record, given that the prior art does not teach or reasonably suggest use of DNA encoding a pokeweed to induce cell death in specific cells of a transgenic plant.

Cho et al (Mol. Cells, Vol. 11 (3), pp. 326-333 (2001) teach production of male sterile plants with a DNA encoding a plant ribosome inactivating protein (RIP). Cho et al do not teach a DNA encoding pokeweed antiviral protein (PAP).

No claim is allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM. Before and after final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Amy Nelson, can be reached at (571) 272-0804.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

8/6/05
Mai

Medina A. Ibrahim

MEDINA A. IBRAHIM
PATENT EXAMINER